Primary Coronary Angioplasty vs Thrombolysis for the Management of Acute Myocardial Infarction in Elderly Patients

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A CUTE MYOCARDIAL INFARCTION (AMI) is the leading cause of death in elderly patients. The choice of an optimal management strategy for patients with AMI has been addressed in multiple clinical trials and summarized in a meta-analysis of trials comparing thrombolysis with placebo. The meta-analysis found a significant benefit of thrombolysis in patients younger than 75 years, but only a trend toward decrease in mortality rates in patients aged 75 years or older.1 Supporters of primary percutaneous transluminal coronary angioplasty (PTCA) emphasize the procedure’s higher early patency rate, lower rates of death and recurrent reinfarction, and markedly reduced rate of stroke. A recent meta-analysis of randomized clinical trials that compared thrombolytic therapy with primary PTCA suggests that PTCA decreases short-term mortality and the incidence of recurrent infarction.2 Observational studies in unselected patients have demonstrated similar outcomes.

Context Despite evidence from randomized trials that, compared with early thrombolysis, primary percutaneous transluminal coronary angioplasty (PTCA) after acute myocardial infarction (AMI) reduces mortality in middle-aged adults, whether elderly patients with AMI are more likely to benefit from PTCA or early thrombolysis is not known.

Objective To determine survival after primary PTCA vs thrombolysis in elderly patients.

Design The Cooperative Cardiovascular Project, a retrospective cohort study using data from medical charts and administrative files.

Setting Acute care hospitals in the United States.

Patients A total of 20,683 Medicare beneficiaries, who arrived within 12 hours of the onset of symptoms, were admitted between January 1994 and February 1996 with a principal discharge diagnosis of AMI, and were eligible for reperfusion therapy.

Main Outcome Measures Thirty-day and 1-year survival.

Results A total of 80,356 eligible patients had an AMI at hospital arrival and met the inclusion criteria, of whom 23.2% received thrombolysis and 2.5% underwent primary PTCA within 6 hours of hospital arrival. Patients undergoing primary PTCA had lower 30-day (8.7% vs 11.9%, \(P = .001\)) and 1-year mortality (14.4% vs 17.6%, \(P = .001\)). After adjusting for baseline cardiac risk factors and admission and hospital characteristics, primary PTCA was associated with improved 30-day (hazard ratio [HR] of death, 0.74; 95% confidence interval [CI], 0.63-0.88) and 1-year (HR, 0.88; 95% CI, 0.73-0.94) survival. The benefits of primary coronary angioplasty persisted when stratified by hospitals’ AMI volume and the presence of on-site angiography. In patients classified as ideal for reperfusion therapy, the mortality benefit of primary PTCA was not significant at 1-year follow-up (HR, 0.92; 95% CI, 0.78-1.08).

Conclusion In elderly patients who present with AMI, primary PTCA is associated with modestly lower short- and long-term mortality rates. In the subgroup of patients who were classified as ideal for reperfusion therapy, the observed benefit of primary PTCA was no longer significant.
comes in patients undergoing primary PTCA compared with those receiving thrombolytic therapy.3,4

The results of randomized clinical trials may be difficult to extrapolate to elderly patients, who are more likely to have extensive coronary artery disease, additional risk factors, and other comorbid conditions that may influence decisions about the appropriate reperfusion strategy. In the absence of conclusive evidence from randomized trials, data from observational studies may be used to assess treatment outcomes in clinical practice. Observational studies reflect general practice in the community and general community standards rather than care provided in highly specialized centers. In light of these issues, we compared the clinical outcomes of elderly patients with AMI who were treated with either thrombolytic therapy or primary PTCA.

METHODS
Study Sample
The Cooperative Cardiovascular Project (CCP) was initiated by the Health Care Financing Administration as an ongoing national program to improve the quality of care for Medicare beneficiaries with AMI.5,6 In this study, we used a database developed from the CCP that includes detailed clinical data on patients with a principal discharge diagnosis of AMI (International Classification of Diseases, 9th Revision, Clinical Modification code 410) between January 1994 and February 1996.

We restricted the study population to patients presenting within 12 hours of symptom onset with evidence of AMI at the time of hospital arrival. We defined AMI as either an elevation of the creatine kinase-MB fraction level (>5%), a 2-fold elevation in creatine kinase level, or diagnostic electrocardiogram changes (ST elevation or new Q waves). Patients younger than 65 years were excluded. Patients presenting with cardiogenic shock were excluded based on the preferential use of primary PTCA in this high-risk population.7 We restricted the study group further to patients without contraindications to thrombolysis (history of bleeding disorder, documentation of prior internal bleeding, active bleeding on arrival, recent trauma or surgery, and cardiopulmonary resuscitation on arrival).

The CCP data collection process focuses on patients’ hospitalizations and does not extract information from other institutions’ records when a patient is transferred. Therefore, transfers from other hospitals were excluded from the primary analysis. Patients transferred to another facility were included because their initial diagnostic and therapeutic strategy could be identified. The analysis was further limited to the first AMI admission for any given individual in the CCP cohort (Table 1).

Data Collection
The data elements we analyzed have been reported previously and included 140 clinical variables for each patient with AMI.3 Data abstraction included patient demographics, past cardiac and noncardiac history, admission characteristics, diagnostic test results, and information on in-hospital events and procedures. Documentation of PTCA required that a coronary intervention was attempted; cardiac catheterizations without associated coronary interventions were excluded. The time from onset of symptoms to hospital arrival was categorized as fewer than 6 hours, 6 to 12 hours, or longer than 12 hours. In-hospital events, including when thrombolysis was initiated and when PTCA was started, were obtained directly from the nursing and procedure records.

Hospital characteristics, including number of hospital beds, annual volume of AMI cases, and the capability to perform on-site PTCA, were obtained by linking the CCP data set with information obtained from the American Hospital Association.9 We categorized each hospital based on the annual number of AMI patients; a cutoff of 150 AMI admissions per year (representing the 50th percentile) separated high- and low-AMI-volume facilities. Similarly, a cutoff of 250 beds (50th percentile) was used to separate large from small hospitals.

For missing data elements, we used indicator variables in our analysis. Categorical variables, when undocumented, were considered to be absent from the patient’s history.

The primary clinical end points of the analysis were 30-day and 1-year mortality rates, both of which were ascertained from the Medicare enrollment database. Secondary end points included post-AMI angina, in-hospital reintervention, heart failure, hemorrhage (ie, gastrointestinal, genitourinary, and pulmonary hemorrhage), intracerebral hemorrhage, ischemic or hemorrhagic stroke, and performance of cardiac catheterization, coronary angioplasty, and coronary artery bypass surgery.

Statistical Analysis
The study sample was divided into 2 cohorts. The cohort receiving thrombolytic therapy included patients who received tissue plasminogen activator or streptokinase within 6 hours of arrival at the hospital. The cohort undergoing primary PTCA consisted of patients who had not undergone prior thrombolytic therapy and received PTCA within 6 hours of hospital arrival. For the 1.5% of patients who underwent both thrombolytic and PTCA, cohort assignment was based on the first strategy initiated. The 6-hour cutoff was designed to select patients who would derive the maximal benefit from either reperfusion strategy and to distinguish primary PTCA cases from subsequent urgent or elective PTCA.

Categorical characteristics were compared using the χ² test and expressed as proportions. Differences in continuous variables were compared using the t test. The use of the Medicare enrollment database to establish the time of death has been validated in the literature.10 Age-adjusted mortality rates for both sexes were calculated by the direct method using 1990 census data.11 Overall survival was determined for each reperfusion strategy by the Kaplan-Meier method.12 Homogeneity of the survival curves was tested with both the log-rank test and the Wilcoxon rank sum test.
Multivariate correlates of 30-day survival were analyzed with a Cox model. Candidate predictor variables for the analysis were those variables shown to be important predictors of mortality in published studies and those variables that differed between patients receiving the 2 treatments: cardiac risk factors (age, sex, diabetes, hypertension, and tobacco use), race, functional status (emphysema, impaired mobility, dementia, and prior stroke), cardiac history (prior myocardial infarction, prior heart failure, and prior PTCA or coronary artery bypass surgery), presenting features (cardiac arrest, hypotension, bradycardia, and heart failure), electrocardiographic features (Q wave, ST elevation, right and left bundle-branch block, atrial fibrillation, and anterior location of infarction), admission serum creatinine levels, coronary artery bypass surgery during the index hospitalization, and hospital characteristics (number of beds, annual number of patients treated with AMI, and capability to perform PTCA). All candidate predictor variables that were identified as important predictors of mortality by univariate analysis (P < .10) were included in the final multivariate Cox model. We report the hazard ratio (HR) and 95% CIs for the primary PTCA vs thrombolytic therapy by univariate analysis (P < .10).

Using institutional characteristics to stratify the population, we further validated our findings by performing a series of subgroup analyses. We first defined an ideal subgroup by restricting our cohort to patients with either ST elevation or left bundle-branch block on arrival and who presented to the hospital within 6 hours of symptom onset. To evaluate the method of reperfusion in institutions with minimal and extensive experience treating AMI, we repeated our analyses after classifying the study sample into those with high annual MI volume (>150/y) and those with low annual MI volume (<150/y). Finally, we repeated analyses after classifying the study sample into those with high coronary angioplasty and those with low coronary angioplasty. The updated analyses were performed after classifying the study sample into those with high coronary angioplasty and those with low coronary angioplasty.
hospitals as either low- or high AMI-volume facilities. In the final subgroup analysis, we evaluated the effect of the treating hospital on the outcome of reperfusion therapy. We stratified hospitals according to their capability to perform PTCA and compared the mortality rates of institutions that made both reperfusion modalities available.

Finally, we compared overall mortality rates between patients receiving reperfusion therapy and those not receiving reperfusion therapy using the χ² test.

RESULTS
Baseline Characteristics
From the CCP database, 80,356 patients had an AMI at the time of hospital arrival and met the inclusion criteria of the study. Table 1 shows the derivation of the study sample. In this cohort, 18,645 patients (23.2%) received thrombolysis and 2038 patients (2.5%) underwent PTCA within the 6-hour time frame. Among the patients receiving thrombolysis, 76.5% received tissue plasminogen activator, 22.6% received streptokinase, 0.7% received anistreplase, and 0.2% received urokinase. The remaining 59,673 patients (74.2%) did not receive reperfusion therapy during the first 6 hours after hospital arrival, and 54,989 (68.4%) did not receive PTCA or thrombolytic therapy at any time.

Table 2 shows a comparison of the baseline characteristics of patients who received early reperfusion therapy by thrombolysis or PTCA group. The mean (SD) age of the cohort was 73.2 (6.0) years, and 42.1% of the patients were female. There was no significant difference in the distribution of age, sex, or race between the 2 groups. The prevalence of cardiac risk factors and non-cardiac conditions was similar between the 2 groups; however, prior PTCA, prior stroke, and prior coronary artery bypass surgery were more prevalent among patients undergoing PTCA.

Patients undergoing primary PTCA presented longer after symptom onset than patients receiving thrombolysis. Furthermore, more time lapsed before initiation of treatment for patients undergoing primary PTCA (mean [SD], 142.6 [68] minutes; median, 129 minutes) than for patients receiving thrombolysis (mean [SD], 68.3 [54.4] minutes; median, 52 minutes). Both groups had a similar clinical presentation, although patients undergoing primary PTCA were less likely to have evidence of congestive heart failure on examination. Fewer patients undergoing primary PTCA had ST elevation (61.6% vs 68.0%, P = .001) and Q waves (23.5% vs 30.2%, P = .001). Patients undergoing primary PTCA were more likely to have left bundle-branch block, although the difference between the 2 groups was not clinically significant.

Morbidity and Mortality
TABLE 3 displays the 30-day and 1-year mortality rates for both groups. Compared with patients receiving thrombolysis, patients undergoing primary PTCA had lower 30-day (8.7% vs 11.9%, P = .001) and 1-year mortality rates (14.4% vs 17.6%, P = .001). Figure 1 shows 30-day and 1-year mortality rates, stratified by sex. After adjusting for age, primary PTCA was associated with lower mortality rates for both sexes. Kaplan-Meier survival curves for both reperfusion strategies are shown in Figure 2. Mortality remained significantly lower for patients undergoing primary PTCA for the follow-up period of 18 months (P < .001). Patients undergoing primary PTCA had a lower prevalence of cerebral hemorrhage and postinfarction angina and a higher prevalence of minor and major bleeding events during hospitalization.
tion (Table 4). Of the 18,645 patients who were initially treated with thrombolytic therapy, 39.2% eventually underwent cardiac catheterization and 12.4% underwent PTCA. A greater proportion of patients in the primary PTCA group had coronary artery bypass surgery during hospitalization (10.4% vs 6.3%, P = .001).

Cox Proportional Hazards Models

After adjustment for baseline characteristics (Table 2), the modality of reperfusion remained an independent predictor of mortality. Compared with early thrombolysis, primary PTCA reduced 30-day mortality (HR, 0.74; 95% CI, 0.63-0.88) (Figure 3) and 1-year mortality rates (HR, 0.88; 95% CI, 0.73-0.94). Stratifying the groups by age, sex, hypertension, diabetes, prior heart failure, and the location of myocardial injury did not change the observed difference in mortality. The benefit of primary PTCA remained significant in each of the subgroups except diabetic patients, patients with prior congestive heart failure, and individuals without anterior location of injury.

Subgroup Analysis

Of the 80,356 patients eligible for reperfusion therapy, 28,955 presented to the hospital within 6 hours of symptom onset and with ST elevation or left bundle-branch block on the initial electrocardiogram. Among these “ideal” patients, 12,941 (44.7%) received primary PTCA or thrombolysis within 6 hours of hospital arrival. A strategy of primary PTCA was associated with a lower 30-day mortality rate than early thrombolysis, although the difference was not statistically significant (10.1% vs 12.0%, P = .06). In a Cox proportional hazard model, primary PTCA was associated with a lower point estimate for 30-day mortality (HR, 0.84; 95% CI, 0.68-1.03). The difference in survival between primary PTCA and thrombolysis diminished at 1 year (16.2% vs 17.8%; P = .18; HR, 0.92; 95% CI, 0.78-1.08).

Because the volume of patients treated for AMI at an institution has been associated with outcome, we performed a stratified analysis based on whether a patient was treated at a low-volume hospital (<150 AMI cases per year) or high-volume hospital (≥150 AMI cases per year) (Figure 4). In this analysis, primary PTCA continued to be associated with lower short- and long-term mortality rates, regardless of the volume of patients with AMI. In addition, patients treated at high-volume institutions experienced lower 30-day and 1-year mortality.

In a stratified analysis comparing reperfusion therapies at hospitals with and without on-site angiography, patients who received thrombolysis at facilities that did not offer PTCA experienced the highest mortality rate; patients who received thrombolysis at facilities that did offer PTCA had better survival rates (Figure 5). Patients treated with primary PTCA had lower 30-day and 1-year mortality rates than either group treated with thrombolysis. Similar trends were noted in the “ideal” subgroup of patients, although the differences in mortality rates were not statistically significantly different (Figure 6).

Finally, we compared mortality rates for patients receiving early reperfusion therapy with those who received none. Patients not receiving therapy had higher 30-day (17.2% vs 11.8%, P = .001) and 1-year mortality rates (33.1% vs 17.6%, P = .001).

COMMENT

Reperfusion therapy (primary PTCA or early thrombolysis) has been established as a pivotal therapeutic strategy in the management of patients with AMI. Although randomized clinical trials have attempted to identify the op-

![Figure 2. Kaplan-Meier Survival Curves for Patients Treated With Primary Percutaneous Transluminal Coronary Angioplasty (PTCA) vs Thrombolysis](image)

Survival estimates are illustrated as points and 95% confidence intervals are shown with vertical crossbars. Each vertical crossbar represents an event. The curves were statistically different by both the log-rank (P < .001) and Wilcoxon rank sum (P < .001) tests.

<table>
<thead>
<tr>
<th>Event</th>
<th>Thrombolysis Group (n = 18,645)</th>
<th>Primary PTCA Group (n = 20,388)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-MI angina</td>
<td>5513 (29.6)</td>
<td>489 (24.0)</td>
<td>.001</td>
</tr>
<tr>
<td>Reinfarction</td>
<td>902 (5.3)</td>
<td>81 (4.0)</td>
<td>.009</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>5218 (28.0)</td>
<td>548 (26.9)</td>
<td>.29</td>
</tr>
<tr>
<td>Cerebral hemorrhage</td>
<td>271 (1.4)</td>
<td>4 (0.2)</td>
<td>.001</td>
</tr>
<tr>
<td>Stroke</td>
<td>554 (3.0)</td>
<td>43 (2.1)</td>
<td>.03</td>
</tr>
<tr>
<td>Hemorrhage</td>
<td>4003 (21.5)</td>
<td>583 (28.6)</td>
<td>.001</td>
</tr>
<tr>
<td>Cardiac catheterization</td>
<td>7304 (39.2)</td>
<td>2038 (100.0)</td>
<td>.001</td>
</tr>
<tr>
<td>Coronary angioplasty</td>
<td>2311 (12.4)</td>
<td>2038 (100.0)</td>
<td>.001</td>
</tr>
<tr>
<td>Coronary artery bypass surgery</td>
<td>1173 (6.3)</td>
<td>211 (10.4)</td>
<td>.001</td>
</tr>
</tbody>
</table>

*Data are presented as number (percentage). MI indicates myocardial infarction.

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Thrombolysis has had statistical power to detect a difference in mortality between these 2 therapies, particularly in elderly patients. A recent meta-analysis pooled data on 1290 patients from 10 randomized trials that compared primary PTCA with thrombolysis and demonstrated a 34% risk reduction in short-term mortality with an interventional strategy of PTCA. The homogeneity of the population (resulting from exclusion of elderly patients in several trials) may prevent the generalization of these results to older patients. The Primary Angioplasty in Myocardial Infarction (PAMI) trial detected a trend toward a reduction in short-term mortality (5.7% vs 15.0%, *P* = .07) among patients older than 65 years who were treated with primary PTCA. The Global Use of Strategies to Open Occluded Coronary Arteries-IIB study (GUSTO-IIB), the largest trial to date, also identified a trend toward lower 30-day mortality with primary PTCA compared with thrombolysis in patients aged 70 years and older. No randomized clinical trial to date has shown a statistically significant benefit of primary PTCA over thrombolysis in the elderly.

Although data from randomized clinical trials suggest a potential benefit of primary PTCA in the elderly, it may not be appropriate to generalize these results to the community at large. A comparison of primary PTCA with alteplase showed only a slightly lower mortality rate in patients older than 75 years who were treated with primary PTCA (14.4% vs 16.5%, *P* = .13). Institutions in which PTCA is performed less often have had worse mortality rates in randomized clinical trials and in observational studies.

In this study, we evaluated reperfusion strategies in elderly patients who presented to hospitals with AMI as captured in the CCP database. The sample of patients receiving reperfusion therapy in the CCP is larger than the combined populations of patients older than 65 years from the previous randomized clinical and community trials. Furthermore, in contrast to prior studies that evaluated 30-day survival rates, the Medicare enrollment database permits analysis of long-term survival rates.

Patients who underwent primary PTCA, in comparison to early thrombolysis, had lower 30-day and 1-year mortality rates after adjustment for baseline characteristics. The lower mortality rates associated with primary PTCA were observed in each of our subgroup analyses, in both men and women, and independent of hospitals' volume of AMI cases, a key indicator of hospital-level quality of care. Therefore, the survival advantage associated with primary PTCA was not solely due to its performance in hospitals with experience in the management of AMI. We further explored whether our study findings were biased by consideration of con-
Thrombolysis, PTCA Available
Thrombolysis, PTCA Not Available

In the unrestricted cohort, patients undergoing primary PTCA had a lower 30-day mortality rate than patients undergoing early thrombolysis, independent of whether the facility had resources to perform coronary angioplasty. A similar pattern was observed at 1-year follow-up. Statistical comparisons are referenced against patients who underwent PTCA. Asterisk indicates P < .05.

In the ideal subgroup (ie, patients with either ST elevation or left bundle-branch block on arrival and who presented to the hospital within 6 hours of symptom onset), patients undergoing primary PTCA had a significantly lower 30-day mortality rate than patients undergoing early thrombolysis in hospitals without resources to perform PTCA. A similar trend was observed at 1-year follow-up, although the difference was not statistically significant (P = .12). Statistical comparisons are referenced against patients who underwent PTCA. Asterisk indicates P = .04.

Our findings support the subgroup analyses from the PAMI and GUSTO-IIB randomized clinical trials and the Second National Registry of Myocardial Infarction (NRMI-2) observational study. These analyses demonstrated a trend toward decreased mortality in elderly patients who underwent primary PTCA.13,15 Furthermore, the data suggest that elderly patients (a group with an inherently increased risk of mortality) may achieve a greater benefit with coronary intervention compared with the general population.

The observed lower mortality rate in patients undergoing primary PTCA could be a reflection of the higher complication rate observed in patients receiving thrombolytic therapy. Patients receiving thrombolysis, in addition to having a higher prevalence of cerebral hemorrhage, were more likely to develop postinfarction angina and congestive heart failure. Bleeding from pulmonary and gastrointestinal sources may have also contributed to the higher mortality rate among patients receiving thrombolysis.

Reperfusion therapy was used relatively infrequently among elderly patients who experienced ST elevation or left bundle-branch block at the time of AMI. Reperfusion therapy (primary PTCA or early thrombolysis) has been established as a fundamental guideline in the management of patients with AMI.22 Less than half of the elderly patients ideal for reperfusion therapy received primary PTCA or thrombolysis within 6 hours of hospital arrival. While this likely reflects the high prevalence of contraindications in the elderly population not ideal for reperfusion therapy, it may also signal the underutilization of this important therapy.23 Compared with patients who received early reperfusion therapy, patients not receiving therapy had higher 30-day and 1-year mortality rates. While an argument can be made for primary PTCA over thrombolysis in the elderly, more attention needs to be focused on the early recognition of AMI in this population and the rapid delivery of either reperfusion therapy.

For patients with AMI who present with ST segment elevation or bundle-branch block, the choice of reperfusion strategies continues to be controversial because most US hospitals do not have the facilities or staff to perform primary PTCA in an expert fashion. Our findings argue that there may be a modest mortality benefit from the use of primary PTCA in elderly patients with AMI. However, because the mortality benefit at 1 year was small and further diminished in the “ideal” subset of patients, we do not believe that our findings support a policy of triage of the elderly to primary PTCA. Rather, these findings are most consistent with the current American College of Cardiology/American Heart Association guideline recommendation that suggests that “primary PTCA should be used as an...
alternative to thrombolytic therapy only if performed in a timely fashion by individuals skilled in the procedure and supported by experienced personnel in high-volume centers.22 Because the overall rate of reperfusion in appropriate patients was low, efforts would best be concentrated on increasing the proportion of eligible patients treated with either form of reperfusion. Choice of reperfusion therapy should be based on the expertise of an individual hospital. In elderly patients with contraindications to thrombolytic therapy, a strategy of primary PTCA should be considered if available on site or, for centers without on-site PTCA, the use of transfer protocols may result in a greater proportion of eligible elderly patients receiving reperfusion therapy.

There are several limitations to our analysis. First, this was an observational study based on a retrospective chart analysis and was, therefore, subject to missing data. Patients were not assigned treatments at random, and unmeasured selection factors could have influenced our findings. However, the large number of variables available in the CCP allowed adjustment for many patient characteristics in multivariate analysis and by stratification for volume of AMI cases at each hospital. Also, our data were collected in a period when stents were infrequently used and when glycoprotein IIb/IIIa inhibitors were unavailable. While the use of stents has reduced the rates of restenosis and revascularization, there is no evidence that the utilization of stents has reduced mortality, particularly in the setting of an AMI.23 The advent of glycoprotein IIb/IIIa inhibitors may have further improved outcomes in patients undergoing primary PTCA. Finally, the observed benefit of primary PTCA cannot be generalized to institutions without adequate institutional or operator volume to ensure optimal primary PTCA results.

In summary, the use of primary PTCA in elderly patients is associated with modestly lower short- and long-term mortality rates compared with thrombolysis. The observed benefit of primary PTCA was diminished in the subgroup of patients who were classified as ideal for reperfusion therapy.

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